Guidance for Industry and FDA Staff

The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6

Document issued on: August 19, 2003

This document supersedes The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6 Draft Guidance issued on February 19, 2003

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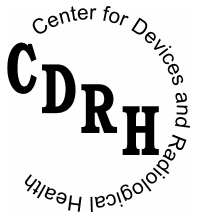

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Division of Mammography Quality and Radiation Programs
Office of Health and Industry Programs

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852.

Alternatively, electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. When submitting comments, please refer to Docket No. 03D-0025. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Guidance for Industry and FDA Staff

The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

On February 19, 2003, FDA published The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6 Draft Guidance for public comment. During the public comment period, two respondents submitted a total of 14 comments. In addition, the National Mammography Quality Assurance Advisory Committee reviewed the Draft Guidance during its April 28, 2003 meeting and provided additional comments. In response to those comments, FDA has modified the guidance as follows by:

1. Further clarifying the term “equipment configuration”.
2. Adding different image receptor sizes as separate equipment configurations.
3. Not recommending that target-filter combinations be tested as separate equipment configurations.
4. Emphasizing the need to minimize non-AEC component variability when conducting the AEC performance test.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Background

This document is intended to provide guidance to mammography facilities and their personnel. It represents the Food and Drug Administration's (FDA) current thinking on the final regulations implementing the Mammography Quality Standards Act (MQSA) (Pub. L. 102-539). The FDA uses mandatory language, such as shall, must, and require, when referring to statutory or regulatory requirements. The FDA uses non-mandatory language, such as should, may, can, and recommend when referring to guidance. It is the responsibility of the facility to read, understand, and follow the final regulations.

Under its own authority, a State may impose more stringent requirements beyond those specified under MQSA and its implementing regulations. A facility may want to check with the State or local authorities regarding their requirements.

The Mammography Quality Standards Act was signed into law on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary) or by an approved State certification body. The authority to approve accreditation bodies, State certification bodies, and to certify facilities was delegated by the Secretary to the FDA. On October 28, 1997, the FDA published the MQSA final regulations in the *Federal Register*. The final regulations, under which mammography facilities are currently regulated, became effective April 28, 1999. The FDA compiled all final guidance related to MQSA into a computerized searchable Policy Guidance Help System in November 1998. The Policy Guidance Help System is available on the Internet at: www.fda.gov/cdrh/mammography/robohelp/start.htm
This compliance guidance document contains guidance to update the Policy Guidance Help System. This document deals with new and previously issued guidance about the Automatic Exposure Control (AEC) component of mammography units.

Guidance information is periodically updated. Individuals wishing to get automatic notification of such updates may subscribe to our E-mail ListServ by visiting http://list.nih.gov/cgi-bin/wa?SUBED1=mammography_cdrh-l&A=1 and following the directions there.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person

listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html.

Automatic Exposure Control (AEC) Performance Testing – Annual Physics Survey and Mammography Equipment Evaluation

Citations:

900.12(e)(5)(i)(A)(B)(C): Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

(i) Automatic exposure control performance.

(A) The AEC shall be capable of maintaining film optical density within ±0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within ±0.30 of the average under phototimed conditions can be produced.

(B) After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) within ±0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

(C) The optical density of the film in the center of the phantom image shall not be less than 1.20.

900.12(b)(10)(i),(ii)(A)(B),(iii): Automatic Exposure Control.

(i) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(ii) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

(A) The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.

(B) The selected position of the detector shall be clearly indicated.

(iii) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

Question 1: What is meant by the terms "AEC", "AEC mode", "mean optical density", and "configuration"?

In its Diagnostic X-ray Performance Standard, FDA defines an automatic exposure control (AEC) as a device that automatically controls one or more technique factors in order to obtain a desired quantity of radiation at a pre-selected location. Such a device would automatically terminate the exposure when the selected quantity of radiation had been delivered. The AEC may control the selection of target material, focal spot, filter material, time, mA, mAs, kVp or a combination of any or all of these factors.

AEC mode refers to the type of AEC being used. Typically available AEC modes can range from fixed kVp and mA (where the kVp and mA are selected by the operator and the time is varied by the AEC), to fixed kVp (where the kVp is selected by the operator and the mAs is varied by the AEC), to various AEC modes in which all factors are varied by the AEC. Some of the more automated AEC modes are known by brand names such as BACE, OPDOSE, AUTO FILTER and AOP.

Mean Optical Density (MOD) means the average of the optical densities measured on the images produced with a given equipment configuration during the AEC performance test using 2, 4, and 6 centimeter thicknesses of a homogeneous material.

For AEC testing purposes, the only equipment configurations that need to be tested are the contact configuration, the magnification configuration (if used clinically), and the various image receptor sizes. Due to advances in AEC design, the example of a target-filter combination as an equipment configuration given in the regulations is no longer applicable. Therefore, we will not enforce testing a target-filter combination as a separate equipment configuration.

Question 2: Can we continue to use technique charts after 10/28/2002?

Yes. Facilities should continue to develop and use technique charts for their clinical exams, especially for AEC modes where kVp and other technique factors must be selected by the technologist. The only place where the words "technique chart" appear in the regulations is in the annual AEC performance test requirement. This regulation places a restriction on the use of a specific factor of the technique chart, the density control setting, when the medical physicist is performing the AEC test after October 28, 2002. After that date, the medical physicist may not adjust the density control setting while performing the AEC test in the 2 to 6 cm range. In other words, the medical physicist may not use the density control setting to compensate for inadequate performance of the AEC. When performing this test, the medical physicist may use a technique chart to adjust other factors such as kVp, filter, anode track or AEC mode to the extent such factors are used clinically. If the AEC performance test fails, the medical physicist may create a temporary technique chart that includes the appropriate density settings (in addition to the other technique factors). This temporary technique chart may then be used by the facility for up to 30 days, or until the problem has been corrected and the equipment passes the AEC performance test, whichever comes first.

When the AEC is functioning properly, the radiologic technologist shouldn't need to adjust the density control setting while imaging patients who are in the 2 to 6 cm range. If the radiologic technologist needs to continually adjust the density control to achieve films of adequate density, the AEC may need adjustment and the medical physicist should be consulted.

The regulations do not restrict the use of technique charts by radiologic technologists. While a properly functioning AEC should reduce the need to use the density setting component of a

technique chart, radiologic technologists may use these charts to change the density control settings whenever they believe it appropriate during the performance of clinical mammographic examinations. In addition, the regulations do not preclude the use of the manual mode and under that scenario, the use of technique charts is essential.

Question 3: During the annual physics survey, how must the medical physicist test AEC performance and what action limits apply?

Due to the proliferation of mammography units with multiple AEC modes, testing of AEC performance has become more complex in recent years. When units had only one AEC detector, a single AEC mode, and a single target-filter combination, testing was relatively straightforward. That is no longer the case for most units. The following guidance is designed to help medical physicists adequately test a unit's AEC performance without over-testing the unit.

During the annual physics survey, the physicist can limit testing of AEC performance to the contact configuration. To fulfill MQSA requirements, all AEC detectors (that can be individually selected by the operator) and all AEC modes used clinically over the 2 to 6 cm range in the contact configuration must be tested. While there are several ways to do the test, medical physicists who use the following guidance will have fulfilled this requirement. Note: Facilities that do not clinically use their AEC in the 2 to 6 cm range (only use manual techniques) must still test the AEC to ensure that at least one AEC mode for each available AEC detector meets the regulatory requirements.

In order to minimize sources of variability, the physicist should use a single cassette (or same cassette type), film from the same emulsion batch, and the same processing conditions throughout Steps 1 and 2 below (see question # 6 below).

Step 1: Determine the Mean Optical Density (MOD)

A) For an AEC detector used in the contact configuration, perform three exposures using 2, 4, and 6 cm thicknesses of a homogeneous material. The exposures are to be performed using an AEC mode clinically used at each of the thicknesses. For example, if a facility typically uses fixed kVp mode at 2 cm, fixed mA mode at 4 cm and OPDOSE mode at 6 cm, then the medical physicist should use these same modes at those thicknesses when conducting the AEC performance test. Note: Even if a facility clinically uses more than one AEC mode at a particular thickness, no more than one of the AEC modes should be tested at each thickness to establish the MOD. For example, if a facility clinically uses both the fixed kVp and the AOP CONTRAST modes at 2 cm, the medical physicist should use the more commonly used of these modes to determine the MOD.
B) Measure the optical density of the images obtained at 2, 4 and 6 cm (total of three images) and average them. This is your MOD.

Step 2: Determine if the AEC detector used in Step 1 is within the regulatory action limit of +/- 0.15 OD of the MOD (+/- 0.30 OD if done before 10/28/2002)

A) Check to see that all three of the optical densities obtained in Step 1B are within the action limit when compared to the MOD
B) If ALL three ODs are within the action limit AND no other AEC modes are clinically used in the 2 to 6 cm range, then this AEC detector has passed. The medical physicist then needs to repeat Steps 1 and 2 for each additional AEC detector clinically used in the 2 to 6 cm range (See question #5 for additional guidance on testing multiple AEC detectors).
C) If ALL three ODs are within the action limit AND the facility clinically uses an additional AEC mode(s) in the 2 to 6 cm range (other than the ones used to originally establish the MOD), the facility must test the additional AEC modes. The medical physicist needs to test EACH additional AEC mode(s) at any ONE clinically used thickness in the 2 to 6 cm range. If the OD(s) is within the action limit when compared to the MOD, then this AEC detector has passed. The medical physicist then needs to repeat Steps 1 and 2 for each additional AEC detector clinically used in the 2 to 6 cm range (See question #5 for additional guidance on testing multiple AEC detectors).

The medical physicist does not have to test the other clinically used equipment configurations during the annual physics survey, but will have to test these configurations whenever a mammography equipment evaluation involving the AEC is performed.

Question 4: During the mammography equipment evaluation, must the medical physicist test the AEC performance in all equipment configurations used clinically by the facility or can it be limited to the contact configuration? What action limits apply?

During a mammography equipment evaluation, the AEC must be operable in all equipment configurations (contact, magnification, and various image receptor sizes) used clinically by the facility. The term "operable," means the AEC must meet the performance requirements of 900.12(e)(5)(i) within the 2 to 6 cm range. Compliance with this requirement may be demonstrated by any of the following three methods:

1. Confirming AEC performance in the contact configuration. In the contact configuration, the AEC must maintain the film optical density (OD) over the 2 to 6 cm range within the action limit of +/- 0.15 OD (+/- 0.30 OD if done before October 28, 2002) of the MOD (See question 3 for additional guidance).

AND

Confirming AEC performance in all other clinically used configurations. This can be done by demonstrating that the AEC meets the density and reproducibility limits established by the manufacturer for those other configurations.

Note: Method #1 can be used only in those cases where the manufacturer has established AEC performance standards for the non-contact configurations provided.

2. Confirming AEC performance in the contact configuration. In the contact configuration, the AEC must maintain the film optical density over the 2 to 6 cm range within the action limit of +/- 0.15 OD (+/- 0.30 OD if done before October 28, 2002) of the MOD.
AND
Confirming AEC performance in all other clinically used configurations. This can be done by comparing the contact configuration MOD with measurements obtained using the 4 cm thick phantom in the other configurations used clinically at the facility. When results across different configurations are compared, the facility may use the action limit of +/- 0.30 OD even after October 28, 2002.

3. Confirming AEC performance by demonstrating that the AEC maintains the MOD within +/- 0.15 OD (+/- 0.30 OD if done before October 28, 2002) in all configurations used clinically by the facility. The action limit applies only within each specific configuration tested and does not apply to data collected across the different configurations.

Because of conflicting recommendations that existed in the professional community regarding measurement of AEC performance during mammography equipment evaluations, facilities that measured AEC performance only in the contact configuration before October 28, 2002 will not be cited for failure to measure AEC performance for all clinically used configurations. However, those that continue this practice after October 28, 2002 will be subject to citation.

Question 5: Must medical physicists test <u>all</u> AEC detectors for AEC performance in mammography units with multiple AEC detectors and can the testing procedures be modified if the detectors are <u>in the same cassette holder</u> (bucky)?

The general principle is that all AEC detectors must be tested. What is considered adequate testing will depend on the arrangement of the AEC detectors in the mammography unit.

1. Where a mammography unit has different AEC detectors in the different size cassette holders (buckys), each detector must be tested separately as described above in questions #3 or #4.
2. Where a mammography unit has more than one AEC detector in a single cassette holder (bucky), the physicist must test all the individually selectable AEC detectors and may test the detectors using either of the following methods:
    i. All detectors as described above in questions #3 or #4, OR;
    ii. One detector as described above in questions #3 or #4 AND comparing the OD obtained at 4 cm from each of the other detectors to the MOD obtained from the first detector. When results across different detectors are compared, the medical physicist may use the action limit of +/- 0.30 OD even after October 28, 2002.
3. Where a mammography unit has multiple AEC detectors that are not individually selectable by the operator, the AEC can be tested as if it was a single detector. An

example of such a system is one with three fixed detectors in which the system automatically chooses which detector will be active during the exposure. Similarly, a large field detector that automatically selects its active area needs to be tested only as a single detector. However, a system with three fixed detectors, each of which can be selected individually by the operator, needs to have all three detectors tested as described in section #2 above. Please note that a detector that can be moved to different positions by the operator is still considered a single detector and needs to be tested at only one of those positions.

Question 6: If the AEC performance test fails, does that automatically mean that the AEC is the cause of the failure?

No. Because the AEC performance test involves many parts of the imaging chain, the medical physicist needs to make sure that the AEC is the part responsible for the failure. For example, problems with the processor, film emulsion or the use of different cassettes during the performance of this test may lead to a failure that is not the fault of the AEC. Facilities are reminded, however, that whatever the cause of the failure it needs to be corrected within the appropriate time frame.

Note: When conducting the AEC performance test, the physicist should try to minimize the variation introduced by components such as film, cassette and processor. Different film emulsion batches, cassettes or processors should not be used while conducting the AEC performance test. An exception would be where prior testing has shown that the different film emulsion batches, cassettes or processors would not introduce excessive variation in the test results. Introducing such variability into the AEC performance test may lead to an inappropriate "failure" of this test.

Question 7: For purposes of AEC testing, are different image receptor sizes considered different "configurations"?

Different image receptor sizes are considered different configurations and have to be tested separately during the mammography equipment evaluation. With respect to AEC performance testing during the annual physics survey, the medical physicist can limit testing in the contact configuration to one image receptor size (usually the small size). However, FDA does recommend that in addition to this required testing, the medical physicist also measure the optical density obtained using the large image receptor and a 4 cm thick homogeneous material and compare it to the mean optical density (MOD) obtained for the small image receptor. When results across different size image receptors (different equipment configurations) are compared, the physicist should use the action limit of +/- 0.30 OD.

Question 8: The regulations in 900.12(e)(5)(i) require that an x-ray unit pass an annual test for AEC performance using 2, 4, and 6 centimeter thicknesses of a

homogeneous material. If a unit is used clinically at combinations of kVp and filtration that include thicknesses outside the 2 to 6 cm range, must it meet the AEC performance requirements at the thicknesses where it operates and must it be tested at those technique factors under the annual quality control requirements? What about AEC performance testing during a mammography equipment evaluation?

During the annual physics survey, the unit is not required to meet the AEC performance action limit outside the 2 to 6 cm range and the medical physicist is not required to test the AEC using thicknesses outside this range. However, we recommend that in addition to the required testing in the 2 to 6 cm range, the unit also be tested at all clinically used thicknesses outside this range and that the action limits specified in the regulations be applied to the extended test. If the unit cannot meet these action limits outside the 2 to 6 cm range, FDA recommends that a technique chart be developed showing appropriate technique factors (kVp, AEC mode, target/filter, and density control setting) for the different breast thicknesses and compositions so that optical densities (OD) within +/- 0.15 OD (+/- 0.30 OD if done before October 28, 2002) of the MOD under AEC testing conditions can be produced.

During the mammography equipment evaluation (as defined in 900.12(e)(10)), the medical physicist must evaluate the AEC in all clinically used configurations (See Question 4). Section 900.12(e)(10) requires that the AEC meet the requirements of 900.12(b) and (e). Under 900.12(b)(10), the AEC is required to be "operable" under "configurations provided." The term "operable," means the AEC must meet the performance requirements of 900.12(e)(5)(i) within the 2 to 6 cm range. FDA also recommends that in addition to the required testing in the 2 to 6 cm range, the unit also be tested in all configurations at all clinically used thicknesses outside this range and that the action limits specified in the regulations be applied to the extended test. If the unit cannot meet these action limits outside the 2 to 6 cm range, FDA recommends that a technique chart be developed showing appropriate technique factors (kVp, AEC mode, target/filter, and density control setting) for the different breast thicknesses and compositions so that optical densities (OD) within +/- 0.15 OD (+/- 0.30 OD if done before October 28, 2002) of the MOD under AEC testing conditions can be produced.

Question 9: A facility only performs screening mammography and <u>never</u> performs any magnification studies. Must the medical physicist test the AEC in the magnification configuration, even though the unit won't be used in that configuration by that facility?

No. The intent of the regulation is to ensure that the AEC mode is operable in all equipment configurations used clinically by the facility. The term "operable," means the AEC must meet the performance requirements of 900.12(e)(5)(i) within the 2 to 6 cm range. One way is to have the AEC tested in all the configurations provided by the system. An alternative method is to ensure that the facility does not clinically use the AEC in those configurations not previously tested by the

medical physicist. This can be accomplished by placing a label on the unit's control panel listing the configurations that cannot be used because they were not tested. These non-operational configurations must also be identified in the facility's quality assurance records.

Question 10: A facility's x-ray unit has a single AEC detector that may be moved to any of three positions along the chest wall to nipple midline of the breast. It cannot be placed under all areas of the breast. Would this meet the intent of the regulation?

Yes. It is not necessary that the AEC detector be mobile over the entire area of the breast.

Question 11: On the facility's x-ray unit, the indication of the detector size and position options is projected onto the input surface of the compression paddle. However, when the paddle is moved up and down, the indicated detector size does not change with distance. Is this an acceptable indication under 900.12(b)(10)(ii)(A)?

Yes. The size and positions indicated at the input surface should be indicative of the size and positions of the detector in the plane of the detector. Compliance could be achieved by representations permanently marked on the paddles or by a projected image that approximates the size and position of the detector.

Question 12: A facility's unit indicates the selected position of the detector by the relative position of the adjustment lever located on one side of the unit and is only visible from that side of the unit. Does this meet the regulation?

Yes. The relative position of the selector would be an adequate display of the detector position, and this display need be visible from only one location.

Question 13: The position of the AEC detector is indicated by a knob under the bucky that can be felt but not seen. Does this satisfy the requirement of being "clearly indicated"?

Yes.

Question 14: How much variability from the "normal" optical density setting must the system provide?

The regulations do not specify the range of variability that must be provided; only that some variability is available.

Question 15: Do all possible positions of the AEC detector have to be indicated on the compression paddle?

The intent of this regulation is to help the radiologic technologist optimally position the AEC detector. Under some AEC detector designs it may be difficult to show all possible positions. Some detectors cover the entire area of the image receptor and once the exposure begins, they automatically select the region of maximum density as the active area. For these systems, indication of the entire potential active area, along with appropriate instructions (usually found in the user manual), would satisfy this requirement. Since the area is automatically selected, the display of the size of the detector is not required. Other designs may have an essentially infinite number of locations under all or part of the image receptor. An indication of the complete range and detector size, coupled with adequate instructions, would be sufficient. Still others may indicate the range of multiple positions on the paddle. Again, this would satisfy the requirement. There may be other methods employed that also satisfy the requirement. The key is that the operators know what areas they may select and the size of the detector.

Question 16: The position of the AEC detector is infinitely variable over the entire area of the image receptor. How can the position of such a detector be identified on the compression paddle?

An indication of the range of coverage and the detector size, along with appropriate instructions (usually found in the user manual), would satisfy this requirement.

Question 17: Do paddles designed to be smaller than the full size of the image receptor have to display the AEC detector position and size?

No. Paddles designed to be smaller than the full size of the image receptor do not have to display AEC detector position and size. Paddles used only for invasive procedures do not have to display AEC detector position and size because they are not covered by the regulations.

Question 18: If the AEC performance is found to be outside the action limit during physicist testing, can a facility adjust the density control settings or use manual techniques until the unit is fixed? Would it require the physicist to come and recheck it or if the repairman did so would that be satisfactory?

The answer to the first question is yes. According to 900.12(e)(5)(i)(A), when the AEC performance is found to be outside the action limit during physicist testing, the medical physicist may create a temporary technique chart that includes the appropriate density settings (in addition to the other technique factors) to be used with the malfunctioning AEC. The facility can use this temporary chart for up to 30 days, or until the problem has been corrected and the equipment passes the AEC performance test, whichever comes first. If the AEC is completely non-functioning, the medical physicist may create a manual mode technique chart that includes all the appropriate manual technique factors. Use of the manual mode would be acceptable under the complete failure situation raised by the question. The facility can use manual techniques for up to 30 days while the non-functioning AEC is being repaired and can continue to use the unit on patients during this period.

The answer to the second question depends on the repair needed to fix the problem. If the repair is classified as "major" (see **Table: Medical Physicist Involvement in Equipment Adjustments, Changes, or Repairs**), then the medical physicist must be onsite to perform the post repair testing. If the repair is not classified as "major" then the post repair testing may be done under the medical physicist's oversight. In either event, the appropriate testing must be performed and passed within the specified time frames.

Air Kerma and AEC Reproducibility Annual Quality Control Test

Citation:
900.12(e)(5)(v): Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

Question 1: Must medical physicists test all AEC detectors for AEC reproducibility in mammography units with multiple AEC detectors in a single cassette holder (bucky)?

No. Because the AEC detectors are also being evaluated as part of the AEC performance test, only a single detector per bucky needs to be tested by the medical physicist. Units that have different AEC detectors in different buckys (e.g., different AEC detectors for the different size cassette holders) will need to have one detector in each bucky tested for reproducibility.

Question 2: Must medical physicists test AEC reproducibility in all clinically used AEC modes?

No. The medical physicist can limit AEC reproducibility testing to the AEC mode used most commonly for the standard breast.

Phantom Images Exposed in a Fully Automatic AEC Mode, if that is the Clinically-used Technique

Many mammographic x-ray systems have more than one AEC mode of operation. A commonly used AEC mode requires the radiologic technologist to set a specific kVp value with the AEC automatically determining the mAs for the exposure (commonly called fixed kVp or Auto-mAs modes). The radiologic technologist can vary the exposure in this AEC mode by setting the kVp, adjusting the density control setting, or both. A more advanced AEC mode is where the system automatically controls the kVp, mAs, and in some cases, target-filter combination (commonly called the Full-Auto mode). In this latter mode, the radiologic technologist can only adjust the exposure by use of the density control. The actual names for the different AEC modes of operation will vary with the different make and model of mammographic unit.

For equipment testing involving the phantom, inspectors should use the same technique factors and AEC mode of operation that the facility uses for its patients with the standard breast (compressed breast thickness of 4.2 cm, with breast tissue consisting of approximately 50% adipose (fat) tissue and 50% glandular tissue in composition). When a facility typically uses the Full-Auto AEC mode for its clinical examinations, the inspector should make an exposure of the phantom using the Full-Auto AEC mode and record the kVp selected by the x-ray system. This same kVp should be used when the beam quality (HVL) testing is conducted in the manual mode of operation. In the event that the displayed kVp after the exposure with the phantom has a three-digit display (e.g., 25.7 kVp), but the manual mode only allows selection of two digits (e.g., 25 kVp), round up or down based on the final digit (example: for 25.1 to 25.4, use 25 kVp; for 25.5 to 25.9, use 26.0 kVp).

FDA is aware that many facilities are monitoring kVp and/or mAs as part of their weekly phantom QC testing. This is not required. If a facility uses the Full-Auto mode and monitors kVp and/or mAs, it will probably observe that, over time, the Full-Auto mode leads to small variations in the kVp selected by the unit for the phantom exposures. Even small variations in kVp may lead to significant variations in the mAs values obtained. While small variations in kVp are to be expected when using the Full-Auto mode, large variations in kVp (greater than 1 kVp of the value usually obtained) may indicate a problem and should be further evaluated. Facilities using the Full-Auto mode that wish to monitor kVp and/or mAs may want to establish baseline mAs values corresponding to the specific kVp values usually encountered during phantom testing. In this way, they can account for the mAs variability that may be caused by small changes in kVp.

Note about facility phantom QC: If the facility typically uses the Full-Auto AEC mode for its clinical examinations, it must use this same AEC mode for its weekly phantom QC test.

Quality Assurance Records

Citation:

900.12(d)(2): Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, protection, and employee qualifications to meet assigned quality assurance tasks, are properly maintained and updated. The quality control records shall be kept for each test specified in paragraphs (e) and (f) of this section until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

Question 4: Is it acceptable for a technique chart to simply state that the facility is using the unit in its fully automatic AEC mode (e.g., BACE, OPDOSE, AUTO FILTER, AOP, or similar modes) for all routine examinations?

Yes. However, if such a technique chart is the only one available, the facility may not use the unit if the automatic AEC mode listed on the technique chart fails during medical physicist testing. For this reason, FDA strongly recommends that the facility develop, and have available, a technique chart that includes other AEC modes (such as fixed kVp mode) and/or manual techniques. The technique chart could then be used as a guide for the radiologic technologist in the event that the fully automatic AEC mode failed or was not suitable for use with a specific patient.

Weekly Equipment Quality Control Tests

Citation:
900.12(e)(2)(i),(ii),(iii),(iv): (2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.
(i) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.
(ii) The optical density of the film at the center of the phantom image shall not change by more than ±0.20 from the established operating level.
(iii) The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA in accordance with 900.3(d) or 900.4(a)(8).
(iv) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall he measured and shall not vary by more than ±0.05 from the established operating level.

Question 10: We perform our weekly phantom images using an AEC mode different from the Full-Auto AEC mode that we typically use for patients. Is this acceptable toward meeting the requirement?

No. If the facility clinically uses the Full-Auto AEC mode for its standard breast patients, the weekly phantom images must be obtained using that mode. FDA requires the weekly phantom image be produced using the same clinical conditions that are used for its patients with the standard breast (compressed breast thickness of 4.2 cm, with breast tissue consisting of approximately 50% adipose (fat) tissue and 50% glandular tissue in composition). Prior to performing mammography on patients, the phantom image must achieve at least the minimum phantom score established by the accreditation body and must be within the action limits established for the three optical density requirements.

Question 11: When performing the weekly phantom image test must we monitor kVp and/or mAs?

No. The only requirements on the weekly phantom image test are that the phantom image achieve at least the minimum phantom scores established by the accreditation body and must be within the action limits established for the three optical density requirements. FDA is aware that many facilities are monitoring kVp and/or mAs as part of their weekly phantom QC testing. This is not required. If a facility uses the Full-Auto mode and monitors kVp and/or mAs, it will probably observe that, over time, the Full-Auto mode leads to small variations in the kVp selected by the unit for the phantom exposures. Even small variations in kVp may lead to significant variations in the mAs values obtained. While small variations in kVp are to be expected when using the Full-Auto mode, large variations in kVp (greater than 1 kVp of the value usually obtained) may indicate a problem and should be further evaluated. Facilities using the Full-Auto mode that wish to monitor kVp and/or mAs may want to establish baseline mAs values corresponding to the specific kVp values

usually encountered during phantom testing. In this way, they can account for the mAs variability that may be caused by small changes in kVp.

Mobile facilities should be aware of the following if they are monitoring mAs as part of their post-move-pre-exam testing. Performing the post-move-pre-exam test in the Full-Auto mode may be problematic (due to the variability of kVp and mAs as previously mentioned). In these cases, the facility may:

1. Use the AEC mode (with fixed kVp) to perform the post-move-pre-exam test, even if they use the Full-Auto mode for their patients with the standard breast. Note: The weekly phantom QC test must be performed using the same clinical conditions that the facility uses for its patients with the standard breast.

OR

2. Use the Full-Auto mode and establish baseline mAs values corresponding to the specific kVp values usually encountered during phantom testing. If the mAs value is within 10% of the baseline value for the post exposure kVp value, the unit has passed that portion of the post-move-pre examination test.

Mammography Equipment Evaluations

Question 2: When performing an annual physics survey or mammography equipment evaluation on a unit with multiple target/filter combinations, what tests or measurements must be performed for each combination?

For a unit with multiple target/filter combinations, the following tests must be performed for each clinically used target/filter combination:

- Focal spot condition (for different target materials (tracks) only)
- X-ray field/light field/image receptor/compression paddle alignment (for different target materials (tracks) only)
- Beam quality and half-value layer
- System artifacts